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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,081	12/14/1998	SASA KRANJC	22681-0002	7627

26633 7590 04/20/2005

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WASHINGTON, DC 20036-3001

EXAMINER
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PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/171,081

Applicant(s)

KRANJC ET AL.

Examiner

Francisco C. Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36, 38, 42-49, 51 and 96 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 36, 38, 42-49, 51 and 96 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 2, 2005, has been entered.

The amendment filed February 2, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 36, 38, 42-49, 51 and 96 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36, 38, 42-49, 51 and 96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the

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written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 36 has been amended to recite that "after the phosphorus initially present in the starting medium is consumed, the concentration of assimilable phosphorus is maintained between 0.0015% w/v and 0.15% w/v during the growth phase of fermentation[.]" However, the specification as filed fails to provide support for this new recitation in claim 36 requiring total consumption of the phosphorus initially present in the medium, followed by maintenance of the phosphorus concentration between 0.0015% and 0.15% during the growth phase of the fermentation. Thus, claim 36 and its dependents must be considered to recite new matter.

It is unclear where support for the new limitation resides. The last full paragraph of page 2 of the specification provides that the phosphorus concentration is to be maintained at a concentration below a limit of 0.15% during the growth phase, and that the growth phase may last up to 40 hours. The first full paragraph of page 3 then states that the concentration may be preferably maintained at a concentration between 0.0015% and 0.15%, and then allowed to reduce to a low value, preferably

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zero, by the 40<sup>th</sup> hour of fermentation. Thus, read in context, the specification asserts that the concentration of phosphorus is to be maintained within the specified range until the growth phase is finished, which is about 40 hours, and then allowed to decrease to a value as low as zero. Respectfully, this is much different than saying that the initial concentration may be allowed to become totally depleted, and then maintained within a specified range.

There is nothing in the as-filed specification explicitly or inherently disclosing a process whereby an initial phosphorus concentration is allowed to become totally depleted, followed by adding phosphorus and maintaining it within the specified range, as now recited in the claims. It is noted, as argued by applicant, that the last lines of page 11 of the specification state that "in the first hours of the culture . . . phosphorus was consumed[.]" However, this cannot mean that **all** the phosphorus was totally consumed, as required by the new claim language, because the Table on page 11 shows measurable amounts of phosphorus still present in the medium after 56 hours. It is further noted, as argued by applicant, that the sentence spanning pages 10 and 11 of the specification state that phosphorus was added to the medium. However, the Table on page 11 clearly states that it displays the amount of phosphorus

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present "in the fermentation broth", and nowhere is there a suggestion that the initial phosphorus was allowed to totally deplete, followed by adding phosphorus and maintaining within the claim-specified range. A holding of new matter is clearly required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 38 does not appear to logically follow from claim 36. Claim 36 requires the phosphorus concentration to be maintained within a range of 0.0015% to 0.15%. However, claim 38 requires the phosphorus concentration to be allowed to decrease to zero. It is confusing how the phosphorus concentration can be maintained within a range of 0.0015% to 0.15%, yet simultaneously be allowed to decrease to zero.

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***Response to Arguments***

All of applicant's argument has been fully considered to the extent applicable to the grounds of rejection set forth herein, but is not persuasive of error. The issue of new matter is discussed above. The claims are considered free of the prior art because the prior art does not suggest a clavulanic fermentation process whereby an initial phosphorus concentration is allowed to become totally depleted, followed by adding phosphorus and maintaining it within the claim-specified range.

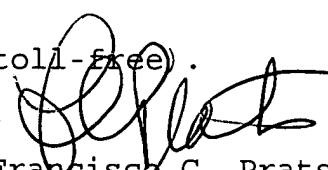
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats  
Primary Examiner  
Art Unit 1651

FCP